Tufts Center for the Study of Drug Development

TUFTS CSDD INSIDER

DECEMBER 2023

From the Executive Director

Dear CSDD Friends,

There are now nearly ten major pharmaceutical companies that have sued the Department of Health and Human Services' Centers for Medicare and Medicaid Services (CMS) for unconstitutional practices associated with the Inflation Reduction Act.

A growing number of pharmaceutical companies have also been taking proactive steps in anticipation of having to negotiate Maximum Fair Pricing. Many have reached out to Tufts CSDD directly for assistance in developing a comprehensive list of R&D cost inputs to inform negotiations with CMS as these inputs have yet to be defined. In response — and based on our extensive research and knowledge on the economics of drug development — Tufts CSDD will be holding several roundtable meetings among R&D finance executive beginning this month. Please **contact me** if your organization would like to participate in these roundtable discussions.

This month we are initiating a new working group study assessing the vendor qualification process and identifying optimization opportunities. Given the large and growing number of vendors supporting clinical trial activity, this new study will update earlier findings, characterize trends, link practices to clinical trial performance, and expand the analysis to include the personnel and resource investment made by service providers responding to requests for information and participating in the qualification process. Please **contact me** for more information about participating in this important new study.

As part of a pre-competitive consortium funded by the Reagan-Udall Foundation, the Tufts CSDD team is actively collecting DCT deployment and clinical trial performance data from more than 35 sponsor and CRO companies. We anticipate having a large dataset from which to establish baseline measures on the impact and ROI of the customized deployment of DCT elements. Please contact **Zak Smith** if your organization is interested in joining the consortium.

Tufts CSDD staff are actively planning our 2024 Post-Graduate Course in Clinical Pharmacology, Drug Development and Regulation to be offered in February. Now celebrating its 51st anniversary, this internationally recognized program provides R&D executives — those new to the industry or new to senior-level roles and those with limited experience managing complex cross-functional activity and teams — with a comprehensive overview of the drug development process and strategies and best practices to optimize performance and efficiency. Contact **Sarah Wrobel** or visit **our website** for more information.

As always, this *Insider* provides updates on our newly launched, planned and ongoing research projects and initiatives. Thank you for your support and encouragement. We wish you a very happy holiday season and a fulfilling, peaceful and healthy new year.

Kenneth Getz
Executive Director and Professor

Tufts Center for the Study of Drug Development
TUFTS UNIVERSITY

Professional Development Courses

This winter, Tufts CSDD will host the 51st annual **Postgraduate Course in Clinical Pharmacology, Drug Development, & Regulation.** This course is designed to provide participants with a comprehensive understanding of the drug development process, from initial discovery through to regulatory approval and post-marketing surveillance. Whether you are new to the industry or need a refresher, the program will provide you with instruction in practical and technical problem-solving in the areas of clinical pharmacology, drug development & clinical trial strategies, biopharmaceutical development, drug safety, and new drug regulation.

To review the program agenda and register for the program, contact **Sarah Wrobel** or visit the **Tufts CSDD website**

Tufts CSDD offers a variety of **Custom On-Site and Virtual Drug Development Training Courses** covering fundamental areas of drug development and regulatory science, and hot topics on issues, challenges, new practices, and solutions. Programs are customized to the specific needs of individual organizations. **This brochure** contains a list of topics from which to choose and design your program. Tufts CSDD can also work with you to add topics not listed below. Once you have selected topics of interest, Tufts CSDD will prepare a proposal and budget and will identify and engage faculty.

To learn more, contact **Sarah Wrobel** or visit the **Tufts CSDD website**

Upcoming Studies

Benchmarking AI use in Drug Development and Quantifying ROI

Tufts CSDD has launched a new multi-company study updating benchmarks on AI/Machine Learning use in clinical development planning, design, execution, reporting and oversight. Conducted in collaboration with the Drug Information Association, the study will look at drug development landscape practices, profile specific use cases, and quantify the return on AI investment in drug development. For more information, contact **Mary Jo Lamberti.**

New Consortium Launched to Gather Empirical Data on DCT Deployment Experience and the Impact of DCT

A new multi-company, pre-competitive consortium was formed this past June to gather and analyze empirical data on company experience with the deployment of virtual and remote solutions supporting clinical trial planning, design, and execution. Tufts CSDD has received grant funding from the Reagan-Udall Foundation to support the consortium. Thirty-five sponsors and CROs are currently participating. Data collection is under way. For more information and if you would like to participate, please contact **Zak Smith**

Updating Benchmarks on the Vendor Qualification Process

This month, Tufts CSDD is launching a new working group study assessing the vendor qualification process. Sponsors, CROs and other service providers dedicate substantial resources and time annually to support this process and to accommodate increasingly complex operating activity. This new study will update benchmarks, characterize trends, link practices to clinical trial performance, and expand the analysis to include the personnel and resource investment made by service providers responding to RFIs and participating in the qualification process. For more information, contact **Zak Smith**

Research Highlights

Our Latest Impact Report

Number of Biotech Products in Late-Stage Clinical Trials has Quadrupled During the Past Decade

The November/December 2023 issue of the Tufts CSDD Impact Report Series (volume 25, number 6) is now available. This issue presents data characterizing dramatic growth and change in the biotech industry: with more than 430 companies now sponsoring clinical trial activity, 200+ recent mergers and acquisitions and global product sales reaching nearly $500 billion in 2022.

Learn more | **Purchase online**

Recent Publications

Botto E. **Professionals and Patients Offer Mixed Views on Retail Pharmacy Chains' Enthusiasm About Trials,** *Applied Clinical Trials.* Published November 8, 2023. **Access article.**

Botto E, Ford RM, Do H, Getz K. **Assessing Sponsor Attitudes Toward Retail Pharmacy Involvement in Clinical Trial Recruitment and Execution**, *Applied Clinical Trials.* Published October 30, 2023. **Access article.**

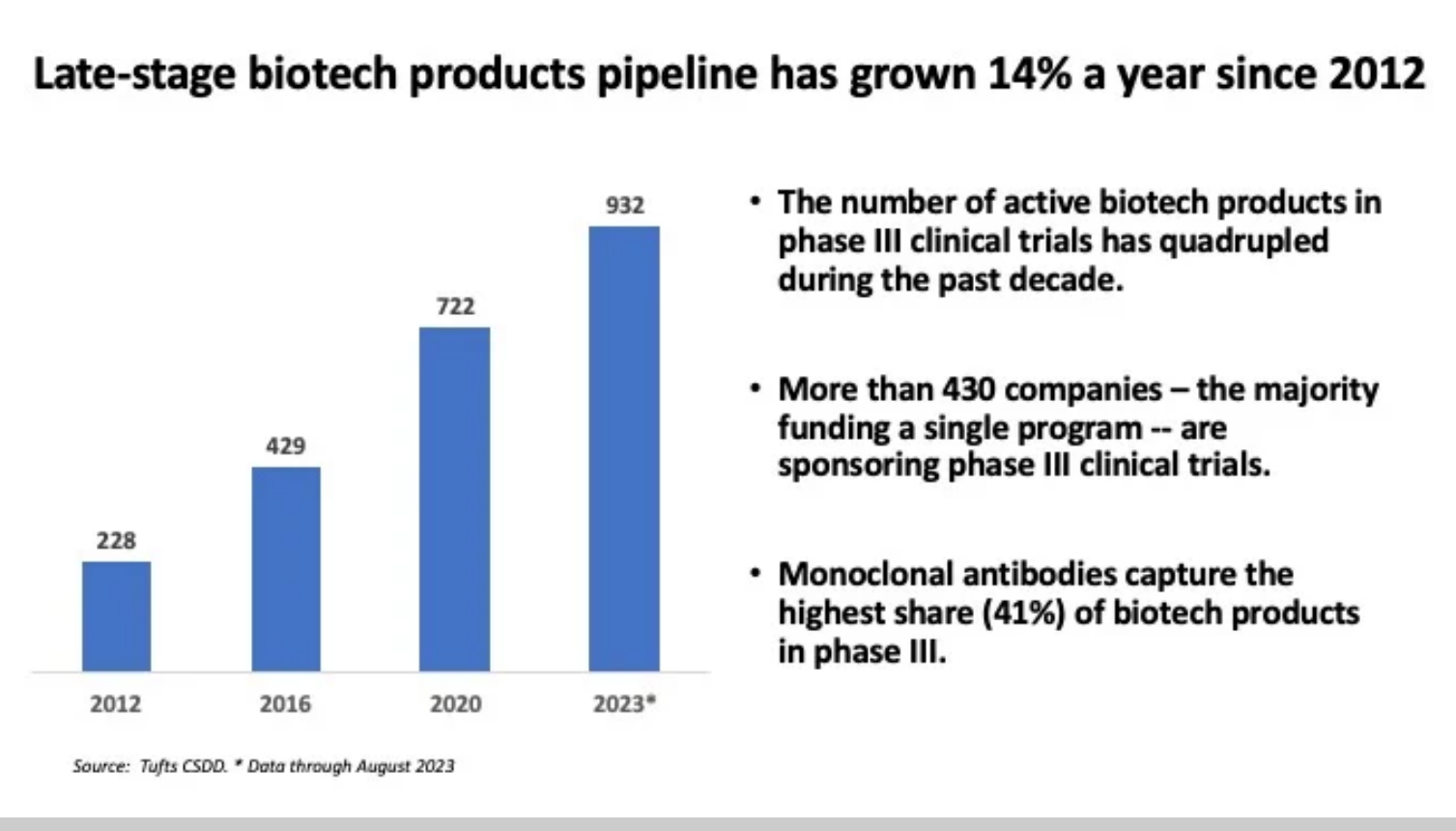
Lamberti MJ, Smith Z, DiPietro M, Barry J, Getz K. **Outsourcing Model Usage and Its Relationship to Clinical Trial Performance**, *Applied Clinical Trials.* Published October 12, 2023. **Access article.**

Smith Z, Botto E, Johnson O, Rudo T, Getz K. **New Benchmarks on Demographic Disparities in Pivotal Trials Supporting FDA-Approved Drugs and Biologics.** *Ther Innov Regul Sci.* Published September 29, 2023. **Access article.**

Zheng W, Kim JY, Kark R, Mascolo L. **What Makes an Inclusive Leader.** *Harvard Business Review*. Published September 27, 2023. **Access article**.

Getz K. **In Search of Attributes Predictive of Collaboration Effectiveness**. *Applied Clinical Trials.* September 2023. **Access article**

Data Insights Digest



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Faculty and Staff Presentations

Upcoming Presentations

Leveraging Patient Engagement Strategies to Optimize Protocol Performance
Ken Getz
Evolution Summit
Live | December 4

Outsourcing Customization Strategies and their Relationship with Clinical Trial Performance Optimization
Ken Getz
ICON, Partner of Choice
Virtual | December 7

Optimizing Study Design and Setting the Stage for Efficient Study Conduct Through Quality by Design
Ken Getz
Robert J. Margolis Center for Health Policy at Duke University and the Food and Drug Administration
Washington DC | January 31

Site Activation and Patients Enrollment Benchmarks Among Sponsors and CROs
Mary Jo Lamberti
Summit for Clinical Operations Executives (SCOPE)
Orlando, FL| February 11-14

Protocol Design Trends and Their Impact on Performance
Ken Getz
Summit for Clinical Operations Executives (SCOPE)
Orlando, FL | February 14

Workshop: Upskilling for Successful Digital Transformations in Europe
Maria Florez
DIA Europe
Brussels, BE | March 12-13

Overview of the Evolving Clinical Research Landscape
Ken Getz
EQuaTR Conference, Northwestern University School of Medicine
Chicago, IL | April 10

Frequency and Impact of Protocol Amendments on Clinical Trial Performance
Emily Botto
Festival of Biologics
San Diego, CA | April 15

Retail Pharmacies and Clinical Trials: Perspectives from Industry, Sites & Patients
Emily Botto
Association of Clinical Research Professionals 2024
Anaheim, CA | May 4

Recent Presentations

Understanding and Overcoming Barriers to Technology Adoption in Clinical Trials
Maria Florez
Clinical Trials Innovation Programme US
Brooklyn, NY | November 17

Diversity and Representation in Oncology Trials
Zachary Smith, MA
Cancer Immunotherapy Summit
Boston, MA | Nov 6 - 8

Measuring Patient and Site Burden in Clinical Trials
Ken Getz, MBA
DIA Annual Meeting Japan
Live | November 5 - 8

Adoption Cycle for Technologies that Support DCTs
Maria Florez
Webcast Series: Effectively Adopt a Decentralized Approach, DCT Week
Virtual | November 7

Optimizing Clinical Trial Performance
Ken Getz, MBA
OCT New England
Live | November 2

Assessing the Net Financial Benefits of Employing Digital Endpoints in Clinical Trials
Joseph DiMasi, PhD
4th Annual Digital Biomarkers & Digital Measurements East Summit
Boston, MA | November 2

Benchmarking Patient Enrollment and Use of Patient Recruitment Tactics
Mary Jo Lamberti, PhD
Outsourcing in Clinical Trials New England
Boston, MA | November 1

Clinical Trial Disruptions During Disasters and Public Health Emergencies
Ken Getz
CTTI and FDA public meeting
Virtual | October 18 - 19

Envisioning the Future Landscape: Preparing the Future Workforce for Drug Research & Development - A Workshop
National Academies
Mary Jo Lamberti, PhD
Washington D.C. | October 16-17

Adopting Technologies that Enable Digital Transformations
Maria Florez
Precision in Clinical Trials Summit
San Diego, CA | October 16

Overcoming Barriers Slowing the Adoption of Disruptive Technologies
Maria Florez
Disruptive Technologies in Clinical Trials
Boston, MA | October 10

Examining the Vendor Qualification and Selection Process
Ken Getz
CORE East
Live | October 4-6

Increasing R&D Productivity to Sustain Biomedical Innovation
Ken Getz
IQVIA Institute Life Sciences Innovation Forum
Virtual | September 26

Patient Preferences for Virtual and Remote Clinical Trial Services
Ken Getz, MBA
DPharm
Live | September 22

Quantifying the Impact of DEI: Making DEI Stick in Drug Development
Jennifer Kim, PhD
EMD Serono
Live | September 13

Speaker Series: DEI
Jennifer Kim, PhD
Massachusetts Department of Revenue
Live | September 11

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